

# Procter & Gamble 70 MAY 14 1235

The Procter & Gamble Company  
General Offices  
2 P&G Plaza, Cincinnati, Ohio 45202

May 14, 2004

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: **Docket Number 02N-0278**  
Prior Notice of Imported Food Under the Public Health Security and Bioterrorism  
Preparedness and Response Act

Dear Sir or Madam:

The Procter and Gamble Company welcomes the opportunity to submit comments pertaining to FDA's Notice of Proposed Rulemaking for providing Prior Notice of Imported Food into the United States published on April 14, 2004 (FR Vol. 69, No. 72, pp 19763-19765). The Procter & Gamble Company ("P&G") is an international consumer product company headquartered in Cincinnati, Ohio that markets consumer products in over 160 countries around the globe. In the United States, P&G products under FDA jurisdiction include those regulated as human and animal foods, dietary supplements, Rx and OTC drugs, cosmetics, and medical devices. P&G food products include Folgers coffee, Iams pet foods and Pringles potato crisps.

On June 12, 2002, the President signed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 into law. P&G supports the goal of enhancing the security of the U.S. food supply. Section 307 of the Act contains new requirements for importing food products into the United States. We believe reasoned final regulations from FDA are essential for implementing the Act in an orderly manner that enhances food safety and food security while minimizing disruption to the U.S. food supply and to the parallel systems in place for nonfood consumer product import, manufacturing and distribution. P&G submitted comments on this important topic during FDA's initial open comment period in August, 2002 prior to drafting of the proposed regulation, again in May 2003 after the proposed regulation was issued, and we appreciate this opportunity to comment once more.

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Our specific comments are as follows:

**1. An Alternate Prior Notice Approach is Necessary for Importing Products Purchased at Retail Outside the US that are Subsequently Shipped to the US. without Intent of Resale.**

The Interim Final Rule requires that all manufactured products offered for import into the United States to be accompanied by two registration numbers. One registration number is that of the last facility holding the product prior to import. Providing this number generally should not be an issue since this facility is likely to have a working relationship with the person desiring to bring the product to the United States.

The second registration number required by the Prior Notice Interim Final Rule is that of the last facility that manufactured, processed, or packaged the product. This requirement has proved to be particularly unworkable for products purchased at retail in another country for subsequent shipment to the United States. The most common examples are competitive products purchased by a business for technical analysis, aesthetic evaluation, or consumer testing in the United States; and consumers who purchase food products to send to the US by international mail. In both cases, the manufacturer's facility registration number is unknown to the importer since the sender has no business relationship with the manufacturer. In fact, since the product being shipped may not be intended for consumption in the US, the facility may not even be required to register. While product manufacturers expect to share facility registration information with those along the supply chain who need to know it in order for product intended for sale in the United States to legally enter the United States, most product manufacturers do not expect to share registration information broadly with the competitors or with the public. This is consistent with FDA's position to discourage providing facility registration numbers broadly via package labeling or website since this would compromise the security value of the registration and prior notice regulation linkage.

An alternate approach to Prior Notice must be developed to accommodate the importation of previously manufactured food products that were purchased at retail outlets outside the United States. We recommend an approach that requires the registration number of the exporting facility and information identifying the company responsible for the product. For products with labeling, this would be the manufacturer information on the package. This information, along with other identity information required by prior notice, should be sufficient for FDA and CBP to make risk decisions about a particular import.

**2. The FDA Prior Notice Regulation Should Recognize and Establish Procedures to Accommodate Cargo Security Initiatives such as C-TPAT.**

The Customs-Trade Partnership Against Terrorism (C-TPAT) is an important and highly successful program initiated after September 11, 2001 that allows companies willing to share detailed information about their supply chains and security procedures to receive expedited processing and reduced inspections of low risk imports. Key to making this program successful is its flexibility. The heart of the program is based on security guidelines that allow facilities to build on their existing systems.

We believe food products subject to FDA's Prior Notice Rule should be eligible to the benefits of C-TPAT similar to non-food products. A number of companies manufacture or distribute both food and nonfood products and strongly prefer having a single set of operating rules for importing all products, especially when both foods and nonfoods may be in the same shipment. A firm having to manage its systems to track C-TPAT products and non-C-TPAT products will incur increased complexity, increased cost, and will be subject to making errors. Firms handling only food products should be encouraged to implement programs like C-TPAT because these programs help increase the biosecurity of the US food supply.

We believe C-TPAT and the FDA Prior Notice Rule could work together in several ways. First, firms that routinely send the same products across the border could provide prior notice on a quarterly basis. These could be products designated as low risk by the agency or foods that are processed and packaged for retail sale. Once a prior notice detailing how much product and many product shipments are anticipated for the upcoming quarter, the facility will track shipments and provide a detailed accounting at the end of the quarter. If the number of shipments or the amount of a product exceeds the numbers provided in the anticipated notice, the FDA must be updated immediately. Shipments arriving at the border would be permitted to cross the border without waiting, but any shipment could still be subject to FDA or CBP inspection.

The C-TPAT system is currently working well. We encourage the FDA to adopt and embrace the system with minimal alteration to the system. The value of the system is its flexibility and we believe any changes the Agency may suggest need to be risk-based ones that allow program members flexibility in implementation.

### **3. FDA and CBP Should Continue to Improve Consistency and Completeness of Prior Notice System Elements**

FDA and CBP deserve a significant amount of credit for having the Prior Notice Electronic System up and running in December 2003. The FDA also deserves credit for its decision to use enforcement discretion to help facilitate trade as CBP, FDA and the industry use and gain experience with the system. As we have gained experience with the prior notice system, we have encountered a couple of issues that require CBP and FDA attention.

We have learned CBP and FDA classifications for importing medicated cough drops are mutually exclusive. A cough drop containing OTC Monograph active ingredients is regulated as an over-the-counter drug by the Agency and is not subject to FDA prior notice. CBP categorizes all cough drops, including ones regulated as drugs by FDA, as candy subject to regulation by FDA as a food, which requires an FDA prior notice.

We have discovered that FDA category codes for food raw materials could be made more complete to cover the range of materials known to be used in products marketed as foods. There are a number of CBP "Customs Codes" such as "methyl ester #3823.19" that still lack accompanying FDA4 or FDA3 codes that have caused confusion among industry users. Some are interpreting the lack of an FDA code as meaning a food ingredient was exempt from prior notice even when it is known the ingredient had use in food. Others presume an ingredient best

known as being drug active ingredient, but also used in a dietary supplement, but lacking an FDA3 or FDA4 code was exempted from prior notice based on its best known usage. We believe these codes should be made as complete as possible and that the Agency should explain that a material without an FDA3 or FDA4 may still require prior notice.

#### **4. Prior Notice Requirements should be Revised for Foods not Intended for Human Consumption, Foods Intended for Consumer Testing, and for Foods Shipped by International Mail.**

The Interim Final Rule covering prior notice requires all foods imported into the United States to have a prior notice. This differs from the Interim Final Rule for registration that covers facilities handling food intended for consumption in the US. Importantly, the Prior Notice Interim Final Rule makes no distinction between foods intended for consumption in the US and those that are not intended for consumption in the US. From a public health risk management perspective, this appears to divert resources from those foods that really could present a public health risk to those that present essentially no public risk. In addition, some foods may be imported with the intent to be consumed by a very small known population subset, such as for a food test.

For circumstances where a food for import will not be consumed or where consumption will be under test conditions, a simplified prior notice scheme should be developed. This approach to prior notice could rely solely on existing CBP requirements and include a field documenting that the food is not intended for consumption or is intended to consumption only under controlled conditions. This approach will still provide records of the import in the unlikely event that a issue is encountered in the future while allowing FDA to focus its resources more fully on food for uncontrolled distribution and consumption.

Examples of activities that could qualify for this simplified prior notice process include:

##### Analytical Reference Samples

Foods, usually food ingredients, being imported for quantitative analysis only

##### Research and Development Samples

Foods, usually food ingredients, being imported for evaluation in new product formulations

##### Ship Tests

Food products shipped to assess product and package integrity through distribution system

##### Consumer Test Product Samples

Food products being imported for use in a controlled consumer test

Under each of the circumstances described above, the threat to the public health is substantially decreased compared to the general free-flowing marketplace. The product is going to a known location. Product is being generally handled by a limited number of people. Other recordkeeping systems such as facility logs and food GMPs require records to be developed and maintained. We encourage the Agency to use a risk-based approach and not a one-size fits all approach to required Prior Notice filing information.

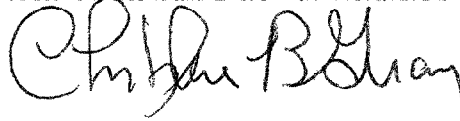
**5. The Efficiency of the Prior Notice Filing Process can be Further Improved, Especially for Shipments Arriving by Boat.**

The Interim Final Rule covering prior notice requires all foods imported into the United States to complete a prior notice within a mode of transportation specific timeframe. Part of this process involves obtaining a CBP entry number, which many firms use a Customs Broker to do. This appears to work well in most cases but can create issues for products arriving by boat. Of all the modes of transportation, boats are most unpredictable and can arrive earlier or later than anticipated. Early arrivals in particular can be a problem because of the 8 hour notice period and the relatively short timeframes in which a company may learn of an impending early arrival. Compounding the issue is that Customs Brokers may not work of a 24-hour, 7-day per week schedule. As a result, Prior Notice for shipments that arrive on the weekend, holiday, or after normal business hours will be filed late and could be subject to civil penalties. We recommend that the prior notice system allow custom entry numbers to be updated to the prior notice after the customs entry has been filed by the Customs Broker and that any penalty considerations be deferred under these circumstances.

The Procter & Gamble Company appreciates the opportunity to comment on this proposed amendment and I would be happy to discuss any of these comments in more detail. I can be contacted at (513) 983-0530 or [guay.cb@pg.com](mailto:guay.cb@pg.com).

Sincerely,

THE PROCTER & GAMBLE COMPANY  
North American External Relations

A handwritten signature in black ink, appearing to read "Chris B. Guay", written over a horizontal line.

Christopher B. Guay  
Legislative and Regulatory Affairs